UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

Memorandum 4/19/00

Subject: Vinclozolin: Additional Characterization of Conservative Components of Dietary Exposure Assessment.
Barcode D265235
Chemical Number 113201

To: Lois Rossi, Director
Special Review and Reregistration Division (7508C)

From: Michael S. Metzger, Chief
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A preliminary human health risk assessment, including a dietary exposure assessment, was provided by HED on 2/14/00. The dietary exposure assessment was characterized as being conservative since the field trial data used will exaggerate residues likely to be actually consumed by people.

Although monitoring data are available from the USDA's Pesticide Data Program (PDP) and the FDA Surveillance Monitoring Program, these data could not be used to refine the risk estimates because not all of the metabolites of risk concern were measured. HED examined the available metabolism data for vinclozolin to determine if the monitoring data could be adjusted using a factor to account for residues not measured. A factor could not be determined for most commodities because of the variability in the ratio of parent compound to the total toxic residue (all metabolites convertible to 3,5-dichloroaniline). This is of particular concern since the percentage of parent compound decreases with time such that for commodities with longer PHIs or storage times (as reflected by the monitoring data), the percentage of parent compound could be very low. HED is currently examining a registrant submission to support use of an adjustment factor.

Although the degree of exaggeration related to use of field trial data cannot be determined at this time, the reasons why we believe the dietary risks are exaggerated can be described qualitatively. These reasons include the following:

(1) Use of field trial data in the dietary risk assessment assumes that all crops are treated at the maximum application rate and harvested at the minimum PHI. In practice, crops are sometimes

treated at lower application rates and harvested at longer PHIs leading to lower residues in these crops.

(2) Use of field trial data assumes no decline in residues between harvest and consumption of the crop. However, residues of vinclozolin will decline between harvest and consumption. Data are not available to quantify the extent of this decline.

(3) Home "processing" was not accounted for in the vinclozolin dietary risk assessment. Practices such as washing, peeling, and cooking could lead to significantly lower residues than those from field trials used in the risk assessment.

(4) For acute dietary risk assessment, the vinclozolin metabolites of greatest concern are those closely related to the parent compound. Use of field trial data in the acute dietary assessment assumes that all residues have structures closely related to the parent compound and thus that they all elicit the developmental effects of concern. In reality, many metabolites convertible to 3,5-DCA may have structures sufficiently different from parent that they are not of acute concern.

Although we cannot quantify for vinclozolin the combined residue reduction from these factors, for many pesticides the difference in residues between field trial and monitoring data can be an order of magnitude (10X) or more.

The Agency contacted USDA/PDP to determine the feasibility of obtaining PDP monitoring data measuring all metabolites of risk concern for vinclozolin in imported wine. In a teleconference between Ed Zager (HED) and Bob Epstein (USDA) on 4/18/00, Dr. Epstein stated that they could perform such a study for imported wine. The specifics of this study are still being discussed.

cc: W. Hazel (HED), E. Zager (HED), D. Scher (SRRD), S. Lewis (SRRD), J. Housenger (SRRD)